

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference REN02-003PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416																								
International application No. PCT/US05/02503	International filing date (day/month/year) 26 January 2005 (26.01.2005)	Priority date (day/month/year) 26 January 2004 (26.01.2004)																									
International Patent Classification (IPC) or national classification and IPC IPC: A23J 1/14(2006.01);C07K 14/415(2006.01) USPC: 530/378;800/295,312;426/630																											
Applicant RENESSEN LLC																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																											
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 11 October 2005 (11.10.2005)		Date of completion of this report 11 May 2007 (11.05.2007)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Cathy K. Worley <i>Felicia D. Roberts</i> Telephone No. (571) 272-0500 <i>for</i>																									

Form PCT/IPEA/409 (cover sheet)(April 2005)

Box No. I Basis of the report**1. With regard to the language, this report is based on:**

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-22 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 23 and 24 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/02503

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest, and, where applicable, the protest fee
- ☐ paid additional fees under protest but the applicable protest fee was not paid
- ☐ neither restricted the claims nor paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

- ☐ complied with.
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid. If no additional fees are paid, the Examiner will search and examine Group I only.

Group I, claims 1-10 and 18, drawn to a soybean meal.

Group II, claims 11-12, drawn to a protein isolate.

Group III, claims 13-17, drawn a method of feeding an animal.

Group IV, claim 19, drawn to a method of processing soybean.

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

The technical feature linking Groups I-IV is a soybean meal with at least 45% protein content on a dry weight basis. However, Edwards et al. teach soybean meal with 47.5%, 52.5%, 53.4%, and 62.7% protein (Edwards et al. (2000) Poultry Science, Vol. 79, pages 525-527, see page 526, Table 1, in particular). Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts
- ☐ the parts relating to claims Nos. ____

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/02503

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	<u>YES</u>
	Claims <u>1-19</u>	<u>NO</u>
Inventive Step (IS)	Claims <u>NONE</u>	<u>YES</u>
	Claims <u>1-19</u>	<u>NO</u>
Industrial Applicability (IA)	Claims <u>1-19</u>	<u>YES</u>
	Claims <u>NONE</u>	<u>NO</u>

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations Continued:

Claims 1-18 lack novelty under PCT Article 33(2) as being anticipated by Reas B. P. (Nutritional and Economic Importance of Genetically-Modified Soybean, published on 16 Aug 2002).

The claims are drawn to high-protein soybean meal, including meal from transgenic soybeans, and including meal from herbicide or glyphosate resistant soybeans, and including meal from a soybean variety comprising ATCC deposit number PTA-5764.

Reas teaches high-protein soybean meal made from genetically modified soybeans referred to as M703 (see page 5, bottom right panel). There appears to be a typographical error in this panel, because Reas references Edwards et al. (2000) where they teach that M703 yielded meal with 62.7% protein (see page 526, Table1). Therefore, the meal taught by Reas actually had 62.7% protein because it is the same meal taught by Edwards et al. There was no exogenous protein added to this meal. The purpose of the comparison of the different soybeans taught by Reas is to use them for commercial purposes, therefore, M703 must be capable of commercial yields. Reas teaches that the genetically modified soybeans are "Round-up Ready" or Glyphosate Tolerant Soybean (see page 3, top left panel). Reas teaches that this meal can be used as feed for broilers (see page 6, top right panel). Although, Reas does not teach seeds deposited as ATCC number PTA-5764, there does not appear to be a way to distinguish the meal taught by Reas from the meal recited in claim 18. If a product being claimed is indistinguishable from a product taught in the prior art, then it is unpatentable, even if it is made by a different process. Reas teaches that soybean meal is used in poultry feeds (see page 1, middle, left panel).

Supplemental Box

Claims 1-2, 4-7, and 10-18 lack novelty and inventive step under PCT Article 33(2)-(3) as being anticipated by Edwards et al. (Poultry Science (2000) Vol. 79, pp. 525-527) in view of Reas.

The claims are drawn to high-protein soybean meal, including meal from transgenic soybeans, and including meal from herbicide or glyphosate resistant soybeans, and including meal from a soybean variety comprising ATCC deposit number PTA-5764.

Edwards et al. teach high-protein soybean meal (see page 526, Table 1, sample M703). The meal from this soybean had 62.7% protein on a dry weight basis (see third column in Table 1). There was no exogenous protein added to this meal and Edwards et al. teach that M703 has considerable advantages over conventional soybean meal as a feed ingredient for broiler chickens (see abstract). Although, Edwards et al. do not teach seeds deposited as ATCC number PTA-5764, there does not appear to be a way to distinguish the meal taught by Edwards et al. from the meal recited in claim 18. If a product being claimed is indistinguishable from a product taught in the prior art, then it is unpatentable, even if it is made by a different process. Edwards et al. teach that the soybean meal is a feed ingredient for broiler chickens; which encompasses a method of feeding an animal with the soybean meal of this invention (see page 525, abstract).

Edwards et al. do not teach herbicide resistance or glyphosate resistance.

Reas teaches glyphosate resistance which is a type of herbicide resistance (see page 3, top left panel). Therefore the combination of the teachings of Edwards et al. and Reas shows that the soybean meal claimed in claims 8 and 9 lacks an inventive step.

Claims 1-6 and 10-19 lack novelty and inventive step under PCT Article 33(2)-(3) as being anticipated by Kerr et al. (US Patent No. 6,147,193, issued on 14 Nov 2000) in view of Reas.

The claims are drawn to high-protein soybean meal, including meal from transgenic soybeans, and including meal from herbicide or glyphosate resistant soybeans, and including meal from a soybean variety comprising ATCC deposit number PTA-5764. The claims are also drawn to methods of feeding an animal (including poultry) and methods of processing soybeans.

Kerr et al. teach a soy protein product having from 42% to 89% protein content on a dry basis (see claims 1-3). They teach that the soy protein product can be soybean meal (see column 14, Table 2). There is no exogenous protein added, and the soybeans are for commercial use including for use in animal feed (see column 2 lines 10-24). Although, Kerr et al. do not teach seeds deposited as ATCC number PTA-5764, there does not appear to be a way to distinguish the meal taught by Kerr et al. from the meal recited in claim 18. If a product being claimed is indistinguishable from a product taught in the prior art, then it is unpatentable, even if it is made by a different process.

Kerr et al. teach that soybeans are processed by removing the hulls, extracting the oils, and processing the remaining defatted flakes (see column 2, lines 16-18). Kerr et al. also teach that the meal is used for animal feed, especially for poultry and swine (see column 2, lines 21-24).

Kerr et al. do not teach transgenic, herbicide resistant, or glyphosate resistant soybeans.

Reas teaches transgenic soybeans with glyphosate resistance which is a type of herbicide resistance (see page 3, top left panel). Therefore the combination of the teachings of Kerr et al. and Reas shows that the soybean meal claimed in claims 7-9 lacks an inventive step.

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.



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Date

23-03-2007

Reference
P 71988

Application No./Patent No.
05712105.5 - PCT/US2005002503

Applicant/Proprietor
Renessen LLC, et al

Communication pursuant to Rules 109 and 110 EPC

(1) Amendment of application documents, especially the claims (R. 109 EPC)

The above mentioned international (Euro-PCT) application has entered the European phase, or can do so, once the necessary conditions are fulfilled.

Under Articles 28, 41 PCT, Rules 52, 78 PCT and Rule 86(2) to (4) EPC, the applicant may amend the application documents after receiving the international search report.

Whether or not he has already done so, he now has a further opportunity to file amended claims or other application documents within a non-extendable time limit of one month after notification of the present communication (R. 109 EPC).

The claims applicable on expiry of the above time limit, i.e. those filed on entry into the European phase or in response to the present communication, will form the basis for the calculation of any claims fee to be paid (see page 2) and for any supplementary search to be carried out under Article 157(2) EPC (R. 109 EPC).

--2/

**(2) Claims fees under Rule 110 EPC**

If the application documents on which the European grant procedure is to be based comprise more than ten claims, a claims fee shall be payable for the eleventh and each subsequent claim within the period provided for in Rule 107(1) EPC.

- ☒ Based on the application documents currently on file, all necessary claims fees have already been paid (or the documents do not comprise more than 10 claims).
- ☐ All necessary fees will be/have been debited automatically according to the automatic debit order.
- ☐ The claims fee due for the claims to were not paid within the above-mentioned period.

Any non-paid claims fee, either based on the current set of claims or on any amended claims to be filed pursuant to Rule 109 EPC (see page 1), may still be validly paid within a non-extendable period of grace of **one month** after notification of this communication.

If a payment is made for only some of the claims, it must be indicated for which claims it is intended. If a claims fee is not paid in due time, the claim concerned is deemed to be abandoned (R. 110(4) EPC).

If claims fees have already been paid, but on expiry of the above-mentioned time limit there is a new set of claims containing fewer fee-incurring claims than previously, the claims fees in excess of those due under Rule 110(2), 2nd sentence, EPC will be refunded (R. 110(3) EPC).

You are reminded that any supplementary search under Article 157(2) EPC will relate only to the last set of claims applicable on expiry of the above time limit AND will be confined to those fee-incurring claims for which fees have been paid in due time.

The fee for the eleventh and each subsequent claim is EUR 45,00.

Receiving Section



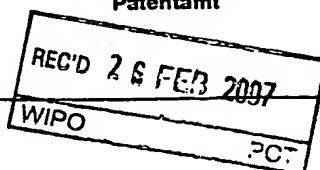


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Date

19-02-2007

Reference P 71988	Application No./Patent No. 05712105.5 - 1268 PCT/US2005002503 / ISA US
Applicant/Proprietor Renessen LLC, et al	

For the aforementioned international application, you are hereby kindly requested to forward to the EPO in its capacity as designated / elected Office:

- ☐ a) The publication of the international search report (Art. 20 PCT).
- ☐ b) the copy of the international preliminary examination report (Art. 36(3)(a) PCT).
- ☐ c) the copy (copies) of the priority document(s). If any document is not available and ISA is not the EP, please indicate below whether the receiving Office has been requested to transmit the document to the International Bureau (Form PCT/RO/101, Box VI; R. 17.1(b) PCT).
- ☒ IRP.....

Receiving Section

Answer of the International Bureau [IB]:

- ☒ The requested item [a), b) or c)] is not available with the IB.

Reason: THE REQUESTED DOCUMENT HAS
NOT BEEN RECEIVED AT THE IB

For priority documents [c)] with ISA not EP:

- ☐ The applicant has requested the receiving Office to issue a priority document [c)] pursuant to Rule 17.1(b) PCT, but the IB did not receive it.

The International Bureau

EPO-DG 1

02 -03- 2007